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Monique X. Le

Appl No.	: 10/562,368	Confirmation No. 6260
Appellant	: Maurice Loretti et al.	
Filed	: June 8, 2006	
Title	: MULTILAYER FILM	
TC/A.U.	: 1794	
Examiner	: Ahmed, Sheeba	
Docket No.	: 1135-16-PCT-PA-TD	
Customer No.	: 22145	

APPELLANTS' BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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July 28, 2009

Commissioner:

This is an appeal to the Board of Patent Appeals and Interferences from the Final Rejection, dated January 27, 2009, in which Claims 1-13 and 17-24 of the above-referenced application stand rejected at least twice. A Notice of Appeal was filed on May 15, 2009. This Brief is filed pursuant to MPEP §1205.

1. REAL PARTY IN INTEREST

B. Braun Melsungen AG.

2. RELATED APPEALS AND INTERFERENCES

There are no related Appeals and/or Interferences.

3. STATUS OF CLAIMS

Claims 1-13 and 17-24 are finally rejected. Claims 1-13 and 17-24 are on appeal. Claims 14-16 were cancelled by the Amendment filed March 16, 2009.

4. STATUS OF AMENDMENTS

In response to the final Office Action dated Jan 27, 2009, an Amendment After Final rejection under CFR § 1.116 was submitted on March 12, 2009 and a Supplemental Amendment was submitted March 16, 2009 wherein claims 4-8, 11, 18 and 21-23 were amended and claims 14-16 canceled to comply with the requirements of form set forth in the Final Office Action and to present them in better form for consideration on appeal. As indicated in the Advisory Actions dated March 23, 2009 and April 15, 2009, the submitted amendments have been entered for purposes of appeal and they have overcome the 35 U.S.C. 112, second paragraph rejection and the 35 U.S.C. 101 rejection raised in the final Office Action.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is an independent claim.

Claim 1 is directed to a multilayer film for containers containing solutions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment. The layers are optionally connected by ties or adhesive layers (Specification, page 8, lines 5-11). According to claim 1, the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than $0.7 ml/m^2 d$ (Specification, page 8, lines 12-15 and lines 4-8); and the intermediate layer has a thickness from 5 to 35 μm (Specification, page 8, line 16). According to claim 1, the inner layer of the multilayer film has a thickness of from 30 to 120 μm (Specification, page 8, line 15); and the outer layer, which has a thickness of from 20 to 40 μm (specification, page 8, line 17) after sterilization at 121° allows desorption of water absorbed by the intermediate layer during the sterilization process (Specification, page 8, line 28 to page 9, line 1).

Independent claim 18

Claim 18 is directed to a multilayer film for containers containing solutions, solids or mixtures for parenteral or enteral nutrition. The multilayer film comprises an inner layer consisting essentially of non-polar polymeric material (Specification, page 10, lines 4-5), an outer layer facing the environment and comprises at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymers (Specification, page 12, lines 25-27) and an intermediate layer comprising ethylene vinyl alcohol copolymer layer having a defined ethylene content of 27 to 38 mol% (Specification, page 11, lines 27-29).

Independent claim 20

Claim 20 is directed to a method for forming the multilayer film of claim 1, for containers containing solutions, solids or mixtures for parenteral or enteral nutrition or tube feeding, the multilayer film has an oxygen transmission rate at 23°C through the multilayer film of less than 0.7ml/m^2d (Specification, page 8, lines 12-15 and lines 4-8), the method comprises providing an inner layer being in contact with the content of the container, and which has a thickness of from 30 to 120 μm (Specification, page 8, line 15); providing an outer layer, which has a thickness of from 20 to 40 μm (Specification, page 8, line 17), providing an intermediate layer, interposed between the inner layer and has a thickness from 5 to 35 μm (Specification, page 8, line 16). According to claim 20, the outer layer allows desorption of water absorbed by the intermediate layer during the sterilization process after sterilization at 121°C (Specification, page 8, line 28 to page 9, line 1).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5, 13, 17, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP Patent No. 0965443 A1 (Loretti).

Claims 6, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti in view of U.S. Patent No. 5,741,566 (Högström et al.).

Claims 7-12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti in view of U.S. Patent No. 5,262,375 (McKedy).

7. ARGUMENTS

I. Loretti does not anticpate claims 1-5, 13, 17, 19, 20, 22 and 23 under § 102(b)

In rejecting the above-identified claims, the Examiner alleges that all the limitations of claims 1-5, 13, 17, 19, 20, 22 and 23 are either disclosed or inherent in the cited reference (Office Action, page 6).

Preliminarily, for a reference to anticipate a claimed invention under § 102(b), it must adequately meet the terms of the claimed invention interpreted in light of the specification of the application. As set forth in the statute, the single prior art reference must disclose each and every element of the claim under consideration. Moreover, it cannot be rebuilt or reoriented by the utilization of Appellant's teachings in an attempt to create an anticipatory structure. Anticipation is established only when a single prior art reference discloses, expressly or under the principle of inherency, every element of a claimed invention as well as disclosing structure which is capable of performing the recited functional limitations. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984), *cert dismissed*, 468 U.S. 1228 (1984); *W.L. Gore and Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984).

The '443 Loretti reference

The '443 Loretti patent application discloses a sterilizable polymer composite tubular film having a three-layer structure: (1) a homophase polypropylene inner layer of thickness from 60 to 100 μm, especially from 65 to 85 μm (col. 3, lines 29-33); (2) an ethylene/vinyl alcohol core layer of thickness from 5 to 35 μm, especially from 10 to 30 μm (col. 3, lines 9-11); and (3) an outer layer of thickness of 40 to 100 μm, especially from 45 to 75 μm (col. 3, lines 21-23), made of polyamide 11, commercially available under the tradename of Rilsan (col. 2, lines 53-54) and/or polyetherblock amide, commercially available under the trademark of Pebax® (col. 2, lines 55-56).

It should be noted that even though the '443 Loretti reference discloses a broad genus thickness range of 40 to 100 μm for the outer layer, it specifically teaches "especially from 45 to 75 μm" (col. 3, line 21-23) and in the example given on page 4, paragraph 0027, teaches an outer layer of 50μm thickness, made of polyamide 11. Furthermore, the cited reference does not

disclose or suggest the characteristics of an outer layer "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C".

Claims 1-5, 13, 17, 19, 20, 22 and 23:

Of the rejected claims, claims 1 and 20 are independent claims.

Independent claim 1 recites:

> 1. Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers; wherein:
>
> the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m^2d;
>
> said inner layer having a thickness of from 30 to 120 μm;
>
> said intermediate layer having a thickness of from 5 to 35 μm and said outer layer having a thickness of from 20 to 40 μm; and
>
> allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

Independent claim 20 recites:

> 20. A method for forming a multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, having an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m^2d, the method comprising:
>
> providing an inner layer, being in contact with the content of the container, having a thickness of from 30 to 120 μm;
>
> providing an outer layer, facing the environment, having a thickness of from 20 to 40 μm;
>
> providing an intermediate layer, interposed between the inner layer and the outer layer, having a thickness of from 5 to 35 μm; and
>
> wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

Thus, independent claims 1 and 20 are both directed to a multilayer film comprising, among other things: (1) an outer layer with a specific range of thickness from 20 to 40 μm; (2) an oxygen transmission rate at 23°C of less than $0.7ml/m^2d$; and (3) wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

Under 35 USC §102(b), the single prior art reference must disclose each and every element of the claim under consideration. As described above, nowhere in the '443 Loretti reference is disclosed a sterilizable multilayer film having an oxygen transmission rate at 23°C of less than 0.7ml/m^2d, having an outer layer having a thickness from 20 to 40 μm, and wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

The Examiner contends that the '443 Loretti reference anticipates the claimed multilayer film on the basis of:

1. Anticipation of ranges: With regard to the difference in the thickness of the claimed outer layer and the outer layer disclosed by Loretti, the Examiner takes the position that:

> when the prior art discloses a range which touches or overlaps the claimed range, in order to anticipate the claims; the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." In this case, the overlapping range is taught with "sufficient specificity" given that the reference states that the outer layer should have a thickness of 40 to 100 microns" (Pages 8-9, final Office Action).

2. Inherency: With regard to the following properties of the claimed multilayer film: (i) "an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m^2d", and (ii) an outer layer "allowing desorption of water absorbed in the intermediate layer during sterilization layer during sterilization after said sterilization at 121°C"; properties that are NOT disclosed or suggested in the cited reference, the Examiner takes the position that:

> ...such properties limitations are inherent in the multilayer structure taught by Loretti given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film [are] identical to that of the claimed multilayer film. (Page 6, final Office Action, emphasis added)

Appellant respectfully submits that the Examiner's rejection is clearly unsubstantiated.

1. With respect to anticipation of ranges, MPEP 2131.03 (II) states:

> ...In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem.*

> *Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. (emphasis added).

Appellant respectfully submits that contrary to the Examiner's assertion, the claimed range of 20 to 40 μm of the outer layer is NOT disclosed in the cited reference with "sufficient specificity to constitute anticipation under the statute". Referring to the specific case law cited in the above-identified MPEP guideline, Appellant respectfully points out that in *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006), despite the overlap both in the reference's broad range and preferred range with the claimed range, the court still held that the reference did not describe the claimed range with sufficient specificity for anticipation. Indeed, a close reading of the Atofina decision teaches a distinction between a prior art broad genus range versus a narrower range recited by a rejected claims. In particular, the Atofina Court states that "a species can anticipate a genus, not the reverse". *Id. at* 999. As such, Appellant submits that the Examiner's application of the law is misplaced.

In this case, the single lower limit of the prior art outer layer range overlaps with the single upper limit of the claimed range. However, this is precisely the situation addressed by the Atofina Court in which a broad genus range CANNOT anticipate a narrower species. In other words, Loretti discloses a broad genus range of 40 to 100 μm for an outer layer and preferred species thickness range of "especially from 45 to 75 μm" (col. 3, lines 21-23) and in the example given at paragraph [0027] specifically teaches a 50μm thick outer layer. However, nowhere is disclosed a species range of 20 to 40 μm as recited by claims 1 and 20 of the instant application. Thus, as the disclosed broad genus range of 40 to 100 μm taught by Loretti does not cover a species with a range of 20 to 40 μm, the rejection violates MPEP §2131.03 (II) for failure to disclose a range with "sufficient specificity", which cites the authority of *Atofina v. Great Lakes Chem. Corp*.

2. With respect to inherent properties, MPEP 2112 states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic...'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' (Emphasis added).

In other words, to state that the claimed properties are inherent to the referenced multilayer film, the claimed properties should be **consistently** present for the entire disclosed thickness range, as inherency may **not** be established by probabilities or possibilities. Moreover, the prior art must disclose materials that necessarily and predictably give rise to the same claimed properties **at all times**, and not by chance or probabilities.

As illustrated in the following Table 1, the cited prior art does not disclose, among other things, claimed elements 3, 4 and 5 set forth in Table 1. Indeed, the thickness range of the claimed outer layer is from 20 to 40 μm, but the cited prior art discloses a range of 40 to 100 μm, which is an improper attempt to reject a narrower species range with a broader genus range contrary to MPEP §2131.03 (II).

Claimed element 4, which recites: "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C", is a characteristic that results from both the thickness and the material from which the outer layer is made of, in this case, PET. (See, e.g., specification at page 12, lines 21-29). In contrast, in addition to using a different thickness range, Loretti discloses a different material for the outer layer, namely Polyamide 11 or polyetherblock amide (Loretti, Col. 2, lines 29-44). The Examiner has not shown with particularity and consistency required by law that Polyamide 11 or polyetherblock amide is capable of producing a layer that allows desorption of water absorbed in the intermediate layer during sterilization after sterilization at 121 °C. Indeed, the Loretti specification is silent and no technical reference has been provided, shown, or referred to for the supposedly inherent characteristic from using Polyamide 11 or polyetherblock amide. Furthermore, Appellant submits that whether Polyamide 11 or polyetherblock amide even has the disclosed characteristic is largely a mystery. Thus, clearly, Loretti cannot be relied on for inherency.

Similarly, Loretti cannot be said to inherently disclose claimed element 5, which is a property resulted from claimed elements 1, 2, 3 and 4. It is undisputable that Loretti does not disclose the combination of elements 1-4. As such, Loretti cannot be relied on to inherently disclose element 5.

Table 1:

Disclosed	Claimed elements	Prior art	
	1. Inner layer: 30 to 120 μm;	yes	
	2. intermediate layer: 5 to 35 μm;	yes	
Outer layer made of PET	3. Outer layer: 20 um to 40 μm;	40 to 100 μm	Polyamide 11 or polyetherblock amide
	4. Allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C;	no	
	5. Oxygen transmission rate at 23 °C through multilayer is less than 0.7ml/m ² d.	no	

In summary, Appellant respectfully submits that Loretti does not disclose a multilayer film with the claimed thickness range of 20-40 μm that can be used as an outer layer that allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C and when used in combination with an inner layer and an intermediate layer of the claimed characteristics, produces an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m^{2}d. As illustrated in Table 1, the claimed property of the instant outer layer, "allow[ing] desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C", results from among other factors, the material from which the outer layer is made of as well as its thickness, namely a PET outer layer and a specific thickness range of 20-40 μm. In contrast, the Loretti outer layer not only has a different thickness range, 40 to 100 μm, but also is made of a different material, a polyamide 11 and/or polyetherblock amide (Col. 2, line 38).

MPEP 2112.IV further states: "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

In this case, other than providing a single overlapping point as evidence of inherency, Appellant respectfully submits that the Examiner has not fulfilled her burden of proof to clearly show how a referenced outer layer, made of a different material, having a different thickness range, will **necessarily** possess the same properties as the claimed multilayer film.. Inherency may not be established by probabilities or possibilities. Based on the undisputable fact that there is **no** guarantee that a referenced multilayer film made of a different material, having a different thickness range will necessarily, consistently and predictably have the same characteristics as a claimed multilayer film, Appellant respectfully submits that the claimed properties are not inherent to the referenced multilayer film, as clearly stated by MPEP 2112.

In view of the foregoing, Appellant respectfully submits that: (1) the claimed species outer layer of thickness from 20 to 40 μm is not anticipated by the referenced broad outer layer of thickness from 40 to 100 μm; and (2) the claimed characteristics of "having an oxygen transmission rate at 23° C of less than 0.7ml/ m^2d" and "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C" are not inherent in the referenced multilayer film to the degree required by law. Thus, claim 1 and 20 are allowable over the cited reference. Reconsideration is respectfully requested.

As claims 2-5, 13, 17 and 19 depend either directly or indirectly from claim 1 and claims 22 and 23 depend from claim 20, they too are allowable for at least the same reasons and allowance is respectfully solicited.

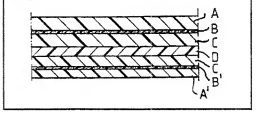
II. Loretti in view of Högström does not render claims 6, 18 and 21 obvious under § 103(a)

In rejecting claims 6, 8 and 21, the Examiner contends that Loretti discloses the claimed elements as previously discussed but does not teach that the outer layer may be a polyethylene terephthalate layer. Högström discloses an outer layer made of polyolefins, polyethylene terephthalates. The Examiner concludes that it would have been obvious for to one having ordinary skill in the art to incorporate a polyethylene terephthalate outer layer in the multilayer film taught by Loretti (Office Action, page 7).

The '566 Högström reference

The '566 Högström reference discloses a multi-layer film, substantially impermeable to oxygen and autoclavable, comprising the following layers A-B-C-D-C-B'-A', as shown in Fig. 1, reproduced below:

Fig.1



The outermost layers A and A' face the environment and the goods inside the container, respectively (Col 2: lines 57-59). They can be made from the same or different polyolefines or PET (polyethylene-terephtalate) or copolymers of PET (Col 3, lines 1-3). The layers B and B' are adhesive layers between layers A and A' and layers C (Col. 3, lines 16-18). The two layers C are made from polymers with moisture absorbing qualities and are substantially impermeable for oxygen (Col. 3, lines 22-25). The layer D consists of poly(ethylene)-vinyl alcohol (EVOH), which is a material with excellent oxygen barrier qualities when dry (Col. 3, lines 32-35).

For the outer layers A and A', polypropylene is preferred if the multilayer film is subjected to steam sterilization. If sterilization by irradiation is desirable, then polyethenes are the material of choice (Col. 5, lines 22-25).

Table 1 (Col. 6, lines 1-9, reproduced below) shows the oxygen permeability measured in cubic centimeters per square centimeter, day and bar for 7 films formed from different materials of composition shown as follows (Col. 6, lines 30-41, reproduced below):

Table 1 shows the oxygen permeability measured in cubic centimeters per square meter, day and bar for Films 1–7 at different temperatures and different relative humidity.

TABLE 1

	Permeability (before sterilization)	
	Ox. 23° C./60% RH cc/m²,day,bar	Ox. 50° C./>95% RH cc/m²,day,bar
Film 1	<0.5	8.50
Film 2	5.00	
Film 3	38.00	395.00
Film 4	37.00	175.00
Film 5	0.50	4.50
	Permeability (before sterilization)	
	Ox. 23° C./60% RH cc/m²,day,bar	Ox. 50° C./>95% RH cc/m²,day,bar
Film 6		6.00
Film 7	0.84	5.00

The seven tested film materials are:

Film 1: polypropylene (PP)/EVOH; 30% ethene/polypropylene (PP)

Film 2: PP/EVOH; 44% ethene/PP

Film 3: PP/polyamide: XE 3303 (PA)/PP

Film 4: Polyethen (PE)/PA (as in Film 3)/PE

Film 5: PE/polyamide: 80% MXD6 and 20% XE 3303 (PA)/EVOH; 33% ethene/PA (same)/PE

Film 6: PP/PA (polyamide 6)/a copolymer containing EVOH/PP

Film 7: Polytehyleneterephtalate (PET)/glass/PET/PP

As shown in Table 1, among all the films tested, film 7 has an outer layer made of polyethylene terephtalate (PET), but the ones with superior oxygen permeability are films 1 and 5, which have outer layers made of polypropylene and Polyethylene (PE)/polyamide, respectively.

Claims 6, 18 and 21:

Of the rejected claims, claim 18 is an independent claim and the other two being dependent claims, with claim 6 depending from claim 1 and claim 21 depending from claim 20. As set forth above, Loretti fails to anticipate claims 1 and 20 under § 102(b) as it fails to disclosed each and every element of the claims under consideration. As Högström is merely relied on to disclose a polyethylene terephthlate layer, it does not make up for the deficiencies of Loretti. The cited references, even if erroneously assumed combinable, still fail to disclose all the elements of independent claims 1 and 20 and thus fail to render claims 1 and 20 obvious under § 103(a). As claim 6 depends from claim 1 and claim 21 depends from claim 20, they too are allowable for at least the same reasons.

Independent claim 18 recites:

> A multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, comprising:
>
> an inner layer consisting essentially of non-polar polymeric material;
>
> an outer layer facing the environment, said outer layer comprising at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer; and
>
> an intermediate layer, interposed between the inner layer and the outer layer, said intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%

In rejecting claim 18, the Examiner contends that Loretti teaches an inner layer and an intermediate layer as claimed and relies on Högström to disclose an outer layer made from PET or PET copolymer. (Office Action, pages 6-7).

Appellant respectfully submits that the cited references are not combinable. Högström teaches using a different material and not PET for an outer layer in a multilayer film that will be subjected to steam sterilization, which is the process for which the claimed multilayer film will be subjected to during use (e.g., "allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C."). In particular, Högström discloses:

> Polypropylene is especially preferred if the multilayer film shall be subjected to steam sterilization, but if sterilization by irradiation is for some reason desirable, polyethenes are the suitable choice for layers A and A', since polypropylenes are not sterilizable with irradiation (Col. 5, lines 22-26, emphasis added).

Additionally, Table 1 (reproduced above) discloses superior oxygen impermeability for Films 1 and 5, which have outer layers made of polypropylene and PE/polyamide, respectively, and inferior performance for Film 7, which has an outer layer made of PET. Table 1 thus teaches using Polypropylene (PP) or polyethylene/polyamide as an outer layer for optimizing the oxygen impermeability of a multilayer film, and NOT PET. Thus, as Högström clearly does NOT teach using PET as an outer layer for a multi-layer film for use in steam sterilization, the Examiner must provide reasons (i.e., a rational underpinning) for why PET was selected in combining with Loretti while Polypropylene (PP) or polyethylene/polyamide are clearly the only rational choices, which the Examiner failed to provide.

"[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). In this case, the claimed multilayer film is formed using different layers made of specific chemicals, it remains necessary to identify some reason for one of ordinary skill in the art to combine an outer layer comprising a PET polymer with an intermediate layer comprising ethylene/vinyl polymer and an inner layer consisting of non-polar polymeric material. If anything, based on Högström's specific teaching as discussed above, Appellant submits that one of ordinary skill in the art would NOT be motivated to use a PET outer layer in the formation of a multilayer intended for steam sterilization. As the Examiner has failed to articulate reasons for combining the references, it is clear the Examiner has erroneously reduced the obviousness analysis to an exercise in finding only the "gist" of the invention. Therefore, rescission of the § 103(a) rejection of claim 18 is respectfully solicited.

III. Loretti in view of McKedy does not render claims 7-12 and 24 obvious under § 103(a)

In rejecting claims 7-12 and 24, the Examiner contends that Loretti discloses the claimed elements as previously discussed but does not teach an oxygen absorber such as iron salts. McKedy discloses an improved oxygen-absorbing composition which includes particulate

annealed electrolytically reduce iron which will provide a more rapid rate of oxygen absorption than plain electrolytically reduced iron (McKedy, Col. 1, lines 22-25). The Examiner concludes that it would have been obvious for to one having ordinary skill in the art to incorporate an oxygen absorber to any of the layers of the multilayer film taught by Loretti (Office Action, page 8).

Claims 7-12 depend from claim 1 and claim 24 depends from claim 20. As set forth above, Loretti fails to anticipate claims 1 and 20 under § 102(b) as it fails to disclose each and every element of the claims under consideration. As McKedy is merely relied on to disclose an oxygen absorbing composition, it does not cure the deficiencies of Loretti. Even if erroneously combined, the cited references still fail to disclose all the elements of independent claims 1 and 20 and thus fail to render claims 1 and 20 obvious under § 103(a). As claims 7-12 depend from claim 1 and claim 24 depends from claim 20, they too should be allowable for at least the same reasons and allowance is respectfully solicited.

Conclusion

In view of the foregoing arguments, Appellant submits that claims 1-13 and 17-24 are patentable over the cited references and allowance is respectfully solicited.

Respectfully submitted,
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8. CLAIM APPENDIX

1. (Previously Presented) Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers; wherein:

the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7 ml/m^2d;

said inner layer having a thickness of from 30 to 120 μm;

said intermediate layer having a thickness of from 5 to 35 μm and said outer layer having a thickness of from 20 to 40 μm; and

allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

2. (Original) The multilayer film according to claim 1, wherein said oxygen transmission rate at 23 °C is less than 0.4 ml/m^2d.

3. (Previously Presented) The multilayer film according to claim 1, having an inner layer essentially consisting of non-polar polymeric material.

4. (Previously Presented) The multilayer film according to claim 3, having an inner layer comprising polypropylene homopolymer and/or polypropylene copolymer.

5. (Previously Presented) The multilayer film according to claim 1, having an intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

6. (Previously Presented) The multilayer film according to claim 1, having an outer layer comprising polyethylene terephthalate homopolymer and/or polyethylene terephthalate copolymer.

7. (Previously Presented) The multilayer film according to claim 1, characterized in that the multilayer film contains at least one oxygen absorber within one or several of the layers.

8. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber contains Fe or Fe(II)-salts.

9. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in said inner layer.

10. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in a tie and/or adhesive layer located between said inner layer and said intermediate layer.

11. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in the respective layer/layers in an amount of 1 to 100 mg/g related to the weight of the respective layer.

12. (Previously Presented) The multilayer film according to claim 7, wherein said oxygen absorber is contained in an amount of 0.5 to 2.0 mg/g related to the overall weight of all layers.

13. (Previously Presented) Vapor sterilized multilayer film according to claim 1.

14. (Canceled)

15. (Canceled)

16. (Canceled)

17. (Previously Presented) The multilayer film according to claim 2, having an inner layer essentially consisting of non-polar polymeric material.

18. (Previously Presented) A multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, comprising:

an inner layer consisting essentially of non-polar polymeric material;

an outer layer facing the environment, said outer layer comprising at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer; and

an intermediate layer, interposed between the inner layer and the outer layer, said intermediate layer comprising ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

19. (Previously Presented) The multilayer of claim 17 wherein the outer layer has a thickness of from 20 to 40 μm.

20. (Previously Presented) A method for forming a multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, having an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m^{2}d, the method comprising:

providing an inner layer, being in contact with the content of the container, having a thickness of from 30 to 120 μm;

providing an outer layer, facing the environment, having a thickness of from 20 to 40 μm;

providing an intermediate layer, interposed between the inner layer and the outer layer, having a thickness of from 5 to 35 μm; and

wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C.

21. (Previously Presented) The method of claim 20, wherein the outer layer comprises at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer.

22. (Previously Presented) The method of claim 20, wherein the intermediate layer comprises ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38 mol%.

23. (Previously Presented) The method of claim 20, wherein the inner layer comprises polypropylene homopolymer and/or polypropylene copolymer.

24. (Previously Presented) The method of claim 20, further providing at least one oxygen absorber within one or several of the layers.

9. EVIDENCE APPENDIX

NONE

10. RELATED PROCEEDING APPENDIX

NONE